DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Date Issued: **December 20, 2001**

Operational Policy Letter #2001.135

To:	**Current M+C Organizations**	X	
	CBC Demonstrations:		
	Evercare		X
	SHMO I & II		X
	PACE		X
	OSP Demonstrations:		
	MSHO	X	
	W.P.S.		X
	HCPPs		
	Federally Qualified HMOs		
	Section 1876 Cost Plans		

Subject: **Coverage of Clinical Trials for CY 2002**

Effective Date: January 1, 2002

Implementation Date: January 1, 2002

The purpose of this OPL is to inform Medicare+Choice (M+C) organizations that for Calendar Year (CY) 2002 we will continue the CY 2001 policy of making fee-for-service payments for covered clinical trial costs.

On September 19, 2000, the Centers for Medicare & Medicaid Services (CMS) published a National Coverage Determination (NCD) regarding coverage of certain benefits related to clinical trials that were not covered by Medicare prior to that date. Since the cost of covering these new benefits was not included in the 2001 M+C capitated payment rates, and since this cost met the threshold for "significant cost" under 42 CFR 422.109(c), Medicare paid for covered clinical trial services outside of the M+C capitated payment rate through CY 2001. Medicare intermediaries and carriers made payments on behalf of M+C organizations directly to providers of covered clinical trial services, on a fee-for-service basis.

We reviewed the M+C payment rates for CY 2002, which were published on March 2, 2001, and determined that these rates do not reflect any adjustment for this significant cost NCD. We have determined, therefore, that the published CY 2002 rates do not adjust appropriately for the costs of this NCD, as required under §1853(c)(7). As a result, for CY 2002 CMS will continue the current policy of making payments on a fee-for-service basis for covered clinical trial costs. Medicare intermediaries and carriers will make payments on behalf of M+C organizations directly to providers of covered clinical trial services, on a fee-for-service basis.

As in CY 2001, payment for clinical trial services furnished to beneficiaries enrolled in M+C plans will be determined according to the applicable fee-for-service rules.

M+C organizations may continue operating under the rules and procedures they have in place for CY 2001 clinical trial benefits, including beneficiary cost-sharing, coverage of complications, and any prior notification rules currently in effect. In addition, M+C organizations may continue to use their CY 2001 Explanation of Coverage (EOC) language on clinical trials.

IV. IDENTIFICATION OF CLINICAL TRIALS CLAIMS

Program Memorandum AB-01-103 available at http://www.hcfa.gov/pubforms/transmit/AB01130.pdf gives instructions to providers and suppliers on billing intermediaries and carriers for CYs 2000 and 2001 clinical trial

services. Beginning January 1, 2002 M+C organizations should continue operating under the procedures in this PM until further notice (extension of this PM or release of a new one.)

Under Original Medicare, providers and suppliers must include ICD-9 code V70.7 (Examination of participation in clinical trial) as the second or subsequent diagnosis code on the UB-92 submitted to intermediaries, and must include the "QV" procedure code modifier on the line item of all clinical trial services submitted to carriers. Starting April 1, 2001, they also must use condition code 30 on UB-92 claim forms. Providers and suppliers may resubmit rejected claims with the clinical trial codes if they were inadvertently omitted. These codes must be present in order for the claims to be resubmitted or otherwise brought to the attention of the M+C organization.

Contact: **CMS Central Office Managed Care Staff**

This OPL was prepared by the Center for Beneficiary Choices.